

The New York City Department of Health considered introducing child-resistant medicine containers in its facilities in an attempt to decrease accidental poisonings. Concern for the possibility that these containers could create problems for patients and even contribute to hazards for young children led to an exploration of how these containers were handled in actual use in a free-living population. This paper compares the experience of users of one type of safety container to that of users of standard containers based on information from interviews and observations in the home.

CHILD-RESISTANT MEDICINE CONTAINERS: EXPERIENCE IN THE HOME

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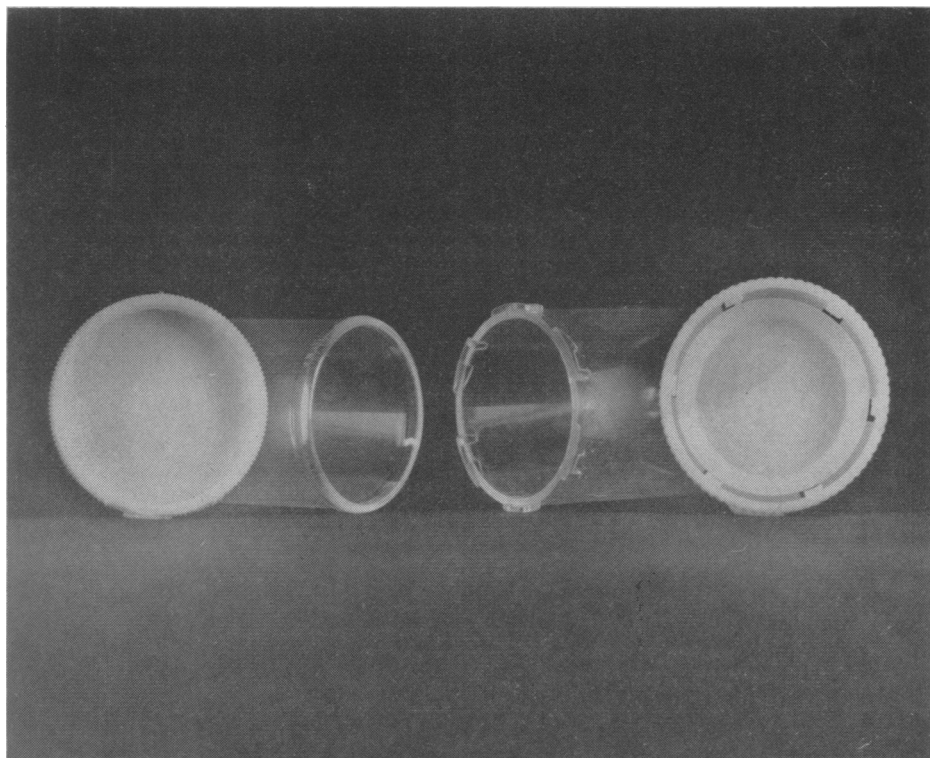
Introduction

ONE approach to the reduction of childhood poisonings due to ingestion of medication is the use of "safety closures." Although no packaging can be absolutely childproof without being impossible for many adults to open as well, several child-resistant containers are available commercially. Indeed, in the period 1960-1967 alone, approximately 60 patents for safety closures were issued.¹ The leading brands of flavored aspirin for children have been marketed in various safety containers for more than a decade.

Following reports of a decrease in poisonings in a defined population from prescription medications dispensed in 270,000 "child-resistant containers,"² the New York City Department of Health considered introducing similar safety containers in facilities under its juris-

diction. This would involve more than two million prescriptions each year. Review of the major operational considerations indicated that the container must have a proven resistance to opening by young children when tested with the inducement of an attractive reward. The mechanics of operation should not be so interesting as to attract the attention of the child and encourage attempts to open it. It should not be difficult to close and there should be some positive indication that the closing has been sufficient to engage the safety action. It should not be too difficult for large numbers of adults to open and the effort to open should not cause spilling of the contents in the process. Finally, the difficulty of opening should not encourage users to leave containers open or discourage the taking of medication according to the prescribed dosage schedule.

Figure 1—Prescription containers: left, standard pop top; right, child-resistant



This inquiry is directed at the final two questions: (1) Are the containers safe but so difficult to use that new hazards are created? (2) Is compliance with instructions reduced?

Method

For the purpose of this study the Palm-'N'-Turn* safety vial was taken as an example of a container meeting the desired requirements for child resistance.³ At one municipal hospital outpatient pharmacy serving indigent and medically indigent patients medications were dispensed in safety and standard (pop top) vials (Figure 1) on an alternating schedule beginning with a safety

vial at the start of each of two daily clinic sessions over a period of 22 days in the summer of 1969. Those patients receiving safety vials were given oral and written instructions (Figure 2) as well as a demonstration by the pharmacist to promote their mastery of the container.

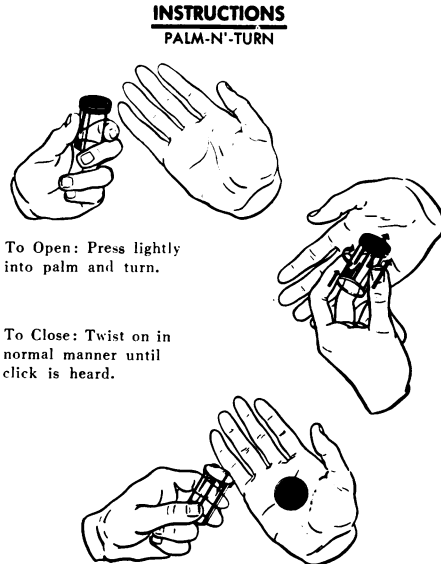
The five medications dispensed to the outpatient population included in this study were:

Reserpine	0.25 mg
Chlorthiazide (Diuril)	500. mg
Chlordiazepoxide (Librium)	16. mg
Chlorpheniramine	4. mg
Multivitamins	

These medications were selected because of their frequency of use in this clinic and the regular regimen for which they were usually prescribed. Medica-

* Manufactured by Reflex Corporation, Windsor, Ontario, Canada.

Figure 2—Instructions for child-resistant container



Children under five years of age are most susceptible to accidental poisoning. Tests have shown that few children of this age can perform the two motions, palming and turning, necessary to open the new Safety Closures!

tions prescribed for a short period or for which an urgent need might arise were of necessity excluded from this study. Recorded from the prescription slip were: name and address of the patient, age of the patient, nature of the vial, and amount and prescribed rate for administration of the medication. Only patients seventeen years and older were included in the study.

The patients were visited at their homes by two medical student interviewers from 3 to 23 days following the pharmacy visit. The average interval was 9.6 days for the safety group and 9.0 days for the controls. No advance notice was given and patients were unaware that they were in the study until the time of the interview. A standard questionnaire provided the basis for the interview. The number of pills expected to be left in the vial at the time of the in-

terview was computed from the information on the prescription slip. The number of pills left in the container was counted and an attempt was made to account for any discrepancy between the number of pills remaining and the expected number.

Observations

One hundred and forty-eight safety and 125 control vials were dispensed to patients who met the study criteria. Six patients who refused or had been unable to handle the safety vial at the pharmacy were excluded from the study. We were able to interview 71 of the safety and 63 of the control patients (Table 1). Up to three attempts were made to contact each patient or a member of his household. Whenever possible, the patient was interviewed but in those cases where this was impossible, the interview was conducted with the closest available adult relative in the household. Fifty-seven out of the 71 safety vial interviews were conducted with the patient, ten were with the patient's spouse and four with another. Fifty-three out of 63 control vial interviews were with the patient, five were with the patient's spouse and five with another.

Eighty-eight visits were required to

Table 1—Response to interviews

	Safety		Control	
	No.	%	No.	%
Completed interviews	71	48	63	50
Incomplete interviews	77	52	62	50
Not home	(51)	(35)	(50)	(40)
Could not locate*	(24)	(16)	(11)	(9)
Refused to be interviewed	(2)	(1)	(1)	(1)
Totals	148	100	125	100

* This category includes those patients for whom we had an incorrect address, those who had moved, gone on vacation or who were otherwise unable to be located.

Table 2—Household structure of patients interviewed

	Safety	Control
Average patient age	56.2	60.6
Range of patient ages	22-87	24-85
Total number of persons in household	225	159
Average age of all persons in household	33.5	43.3
Average number of persons in household	3.17	2.52
Average number of rooms in household	4.10	3.90
Density of household (number of persons/number of rooms)	.733	.650
	(n=71)	(n=63)

Table 3—Container in use at the time of interview

	Safety		Control	
	No.	%	No.	%
Original	62	88	58	92
Other	6	8	3	5
Unknown	3	4	2	3
Total	71	100	63	100

No significant difference

complete the 71 safety interviews and 78 visits for the 63 control interviews.

The average age of all the patients successfully interviewed was 58.2 years (range 22-87). Those patients who could not be interviewed had an average of 56.6 years (range 23-76). The characteristics of the interviewed households are given in Table 2. The recipients of safety vials were slightly younger and had a larger number of persons per household.

The safety vial population interviewed was 36 per cent white, 37 per cent

black, and 27 per cent Puerto Rican. The control population was 39 per cent white, 30 per cent black and 31 per cent Puerto Rican. All were residents of the communities of Greenpoint, Williamsburg, Bushwick and Bedford-Stuyvesant in Brooklyn.

Some patients in both groups transferred their pills to other containers (Table 3). All three of the control patients who had transferred their pills into other vials gave "convenience of storage" in a larger or smaller container as the reason for the transfer. Only one of the six patients in the safety group who transferred did so for "economy of room." One patient in the safety group transferred because "it is faster" to open a control container. One patient transferred because she had arthritis and admitted that she could not open the safety vial. Another patient was forced to transfer her pills from the safety vial after she had broken it by opening it with a can opener. Two patients transferred for undetermined reasons.

Ten of 62 safety vials examined in patients' homes were improperly locked. Only one of 63 control vials was not fully closed. This difference was significant (Table 4). In two cases the safety vial locking mechanism had been broken

Table 4—Condition of container at the time of interview*

	Safety		Control	
	No.	%	No.	%
Properly closed	52	84	60	95
Improperly closed	10	16	1	2
Unknown	—	0	2	3
Total	62	100	63	100

Significant difference. Excluding the unknowns $\chi^2=7.7$, $df=1$, $P<0.0001$

* Not included in Tables 4 and 5 is the data on the nine safety group patients in Table 3 who had either transferred their pills or for whom we were not able to determine this data.

Table 5—Person opening container*

	Safety		Control	
	No.	%	No.	%
Patient	54	87	60	95
Other	6	10	2	3
Unknown	2	3	1	2
Total	62	100	63	100

No significant difference

* Not included in Tables 4 and 5 is the data on the nine safety group patients in Table 3 who had either transferred their pills or for whom we were not able to determine this data.

Table 6—Ease of handling

	Safety		Control	
	No.	%	No.	%
No difficulty	19	27	56	89
Difficulty overcome	34	48	1	2
Continuing difficulty	10	14	2	3
Unknown	8	11	4	6
Total	71	100	63	100

"No Difficulty" versus "Difficulty Overcome" + "Continuing Difficulty." Significant. $\chi^2=53.8$, $df=1$, $P<0.00001$.

by patients who had twisted the top as if it were a screw top vial. Both patients continued to use the original, now broken, safety vial. Six of remaining eight safety vial users were unaware that their containers were unlocked when the cap was sitting on top of the vial. The other two had intentionally left their vials unlocked.

Most patients in both groups opened their own container (Table 5). A few patients divided their supply of pills into a vial for home use and one for their place of work. One control patient added his supply of multivitamins into the same bottle that held his wife's multivitamins.

Those patients given safety vials re-

ported significantly more difficulty opening and closing their vials than did control patients. Only 27 per cent of the safety patients reported no difficulty mastering the safety container; 48 per cent had some difficulty which they eventually overcame; 14 per cent never mastered the container. Few control patients said they had had difficulty with their container (Table 6).

Medications were stored in a variety of locations in the home. No significant difference between the groups was found with respect to place of storage for medications (Table 7).

In several cases there was doubt about the prescribed dose or the number of pills actually dispensed. These are excluded from the following tabulations (Tables 8 and 9) of adherence to the prescribed schedules.

Patients of both groups were remarkably lax in following prescribed rates for taking their medications. Only four safety and five control patients had taken the expected number of pills. Forty-five safety and 35 controls had taken fewer than the required number of pills (see Table 8).

To account for the variability in both the prescribed rate of intake and the time lapse until date of interview, the difference between the actual and ex-

Table 7—Storage location

	Safety	Control
Kitchen	25	30
Living room	4	10
Bedroom	22	12
Bathroom	9	5
Hall	1	0
Handbag	6	5
Unknown	4	1
Total	71	63

No significant difference

Table 8—Adherence to prescribed schedule

	Safety		Control	
	No.	%	No.	%
Behind schedule	45	83	35	67
On schedule	4	8	5	10
Ahead of schedule	5	9	12	23
Total	54	100	52	100

"On Schedule" versus "Not on Schedule." Not Significant. "Behind Schedule" versus "Ahead of Schedule." Significant $\chi^2=4.0$, $df=1$, $P<0.05$.

pected numbers of pills in the container at the time of interview was adjusted by dividing it by the rate prescribed per day and the interval between the patient's visit to the pharmacy and our visit to him. This resulted in a value called the "compliance index." It represented the degree of difference between the number of pills prescribed and that actually taken by the patient each day. A positive value indicated the patient had not taken as many pills as prescribed.

A negative value indicated he had taken more than the prescribed amount. As seen in Table 9, the compliance of the patients, indicated by the average compliance index using the Wilcoxon

rank test, was poorer in the safety vial group than in the control group. A similar trend was observed for each drug but differences did not approach statistical significance. The compliance index was not influenced by the length of the interval between receipt of medication and the home interview.

Discussion

The choice of medications included in this study necessarily selected index patients in the older age group. This was acceptable since the experiment was not a test of episodes of poisoning in children—which would have required very large populations—but of the handling of medication containers and compliance with dosage schedules.

Since half of the initial population in both the safety and control groups could not be interviewed, the question of comparability of the groups may be raised. Despite the realities of a difficult clinic situation, it is known that the ages of the patients in the interviewed and not interviewed households were approximately equal. The 50 per cent success rate in locating and interviewing families is considered reasonable in this disadvantaged community.

Many patients in both groups attributed their lack of compliance to a

Table 9—Compliance of safety and control vial users by type of medication

	Safety		Control		Probability of exceeding such a difference by chance
	Number	Average compliance index	Number	Average compliance index	
All medications combined	54	.59	52	.33	0.02
Reserpine	18	.63	13	.53	0.38
Diuril	22	.60	22	.39	0.16
Librium	4	.59	6	.23	0.13
Chlorpheniramine	3	.92	3	.85	0.40
Multivitamins	7	.30	8	-.28	0.12

nescience of the purpose and nature of their medications. On more than one occasion, the interviewers were asked to record this information on the vial using the terms "pressure pills" and "water pills" to aid the patient in understanding the purpose of his medication. Frequently, patients claimed to have stopped taking their pills once they started to feel better. Many patients simply forgot to take them. One patient insisted upon finishing all her old medication (Darvon) before starting her new one (Diuril) even though they were different drugs. An elderly man found the side effects from five different medications to be so upsetting that he simply stopped taking his Reserpine.

The dilemma of a 53-year-old arthritic grandmother was not atypical. She was afraid to leave the safety vial open for fear that one of her four grandchildren might accidentally take some of her medication, and yet she herself was dependent upon the presence of her daughter to open it for her. During the course of a week she took two of fourteen pills prescribed.

A complete discussion of motivational factors in patient behavior is beyond the scope of this report. As indicated in Table 4, significant difference was found between the ability of the two groups to overcome the mechanical difficulties of their respective containers. Part of this difference could be attributed to the newness of the safety container and it is possible that longer and more common use of these vials would lead to acceptance and mastery. A difficult factor to evaluate is the effectiveness of the oral instructions given at the pharmacy. The staff time required for effective communication could be a significant problem—at least during an introductory period—in a facility dispensing several thousand items each week. A study after the familiarization period might be more appropriate to determine effects on compliance.

This study proceeded on the assumption that the safety container had already been demonstrated to be child-proof. The question under consideration was whether it was so difficult to use that new hazards would be created. The finding that 16 per cent of the safety containers were improperly closed compared to 2 per cent of the standard containers confirms this concern. On the other hand, if it is assumed that the standard container offers no protection at all, then it might be argued that the 14 per cent differential would be more than compensated for by the fact that all of the closed safety containers would resist the opening efforts of children, while none of the standard containers would resist such efforts. However, this assumption is open to question. Furthermore the question may be raised whether improperly closed safety containers that patients believe to be closed (8 of 10, in this study) create special hazards greater than those of the closed standard containers.

The erratic storage of medications in the home by both groups is a continuing cause of concern to the Health Department. One might expect to find that it was the older population of patients living without children who were the most careless about closing medicine vials. However, the average age of the ten safety vial patients who left their containers unlocked was 52.5 years old as compared to 56.8 years old for the whole safety group. These ten had more (.6 as compared to .4) children six years or younger living in their households.

Six cases of previous accidental poisonings were reported in the households visited. Storage of medication in these households was similar to that in the entire group. In one of these six, a safety vial was found unlocked on the television set. It was interesting to note that only two out of 134 persons interviewed were aware of the existence of the Poison Control Center and that

neither had the telephone number. Although most often consulted by professionals, consideration could be given to placing the telephone number of the Center on the inside cover of the telephone directory along with the other emergency numbers.

Reports of difficulty opening the container by arthritis patients were inconsistent, and one such patient reported that the safety vial was easier to open because he did not have to use his fingers.

Summary and Implications

In actual use in the community, patients given child-resistant containers experienced significantly greater difficulty in opening their containers than did patients given standard containers. The data showing that drugs are stored so casually in the home indicates there are still miles to go in educating people in the proper way to handle drugs at home. The fact that it is easier to change environment than people's behavior is exactly what makes the use of safety closures so attractive. Yet 16 per cent of safety container users left their vials unlocked and 14 per cent never mastered the safety closure despite efforts to in-

struct them. Users of the safety containers were significantly poorer in their compliance with prescribed dosage schedules. Therefore we are reluctant to recommend to the Department of Health that this safety closure be used in all municipal facilities at this time. This negative finding, despite the acknowledged methodologic problems encountered in studying actual performance in a free-living population, suggests the necessity for further and more refined study.

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